

**Attachment VII: Summary of Safety and Effectiveness Information [510(k) Summary]**

Synthes (USA)  
1690 Russell Road  
P.O. Box 1766  
Paoli, PA 19301

(610) 647-9700  
Contact: Angela J. Silvestri  
August 1, 1995

Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti. LC-DHS) is compared to Synthes Limited Contact Dynamic Hip Screw (LC-DHS) Implant and Synthes Dynamic Hip Screw (DHS) Implant.

Synthes Ti. LC-DHS is a sliding hip screw plate device, intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed. The device is manufactured from a Titanium Alloy.

Synthes DHS is intended to treat stable and unstable intertrochanteric, subtrochanteric and basilar neck fractures in which a stable medial buttress can be reconstructed. The device is manufactured from stainless steel.

Synthes will provide the Ti. LC-DHS sterile or non-sterile. Sterile devices will be gamma radiated. Of course, non-sterile devices must be sterilized prior to use, Recommended Sterilization parameters are:

<u>Method</u>	<u>Cycle</u>	<u>Temperature</u>	<u>Time</u>
Steam	Pre-vacuum	132° C - 135° C	6 min.
Steam	Gravity Displacement	132° C - 135° C	15 min.

Based on mechanical test results, the Ti. LC-DHS design has been found to be substantially equivalent to the DHS design.

1164